Approved
OMB No. 0920-0004
Exp. 04/30/2006

Surveillance registry for birth outcomes of pregnancy-associated West Nile virus infection in the United States

Please return completed forms by mail or fax to:
CDC/Arboviral Diseases Branch
Attn: Stephanie Kuhn
Foothills Campus
Rampart Road
Fort Collins, CO 80521
FAX: (970) 266-3568

For adults ≥18 years of age able to give consent

Name _____ Date of birth _____

Please feel free to ask any questions you may have about this registry and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. You will be given a copy of this consent form.

Introduction & Purpose

West Nile virus is a virus that first appeared in the United States in 1999. The virus is transmitted to people by infected mosquitoes. In some cases, West Nile virus can cause serious illness affecting the brain or spinal cord.

The United States Centers for Disease Control and Prevention has developed a registry to collect information about West Nile virus infections during pregnancy. This registry will allow us to learn how often West Nile virus is passed in the womb from pregnant mother to child. This will also help us see if West Nile virus affects the health of pregnant women and the health and development of infants. This information will help to guide in future prevention efforts.

Procedures

We are asking you to be in this registry because you had a West Nile virus infection during your pregnancy. You are free to join this registry or not. If you agree to be part of this registry, we will ask the doctors caring for you and your child some questions about your health and your child's health at the time of delivery. In addition, we will ask your permission to collect samples of blood or tissue from you and your child at the time of delivery. You can refuse to give any or all of these samples if you do not want to participate.

If you participate, we will ask your doctor to collect the following samples at the time of delivery:
1) A 5 ml (one teaspoon) sample of your blood which may be taken during blood draw for your care
2) A 5 ml sample of your child's blood taken from the umbilical cord after its removal
3) A section of the umbilical cord after its removal
4) A section of the placenta after its delivery
5) A 2-5 ml sample of your first milk or, if that is not available, a sample of breast milk taken from the week following your delivery
6) A 5 ml sample of your child's blood **only** if blood from the umbilical cord was not available at delivery or if West Nile virus infection is suspected from laboratory testing of your child's other samples. We may request this specimen up to 8 months following your child's birth.
7) Only if your doctor needs to take spinal fluid from your back or your child's back for your clinical care, we would like to test any leftover fluid. If available, we will test leftover spinal fluid to look for West Nile virus infection.

We will test these samples to determine if your child was infected in the womb with West Nile virus. We will inform your physician when the test results are available

In addition to testing for West Nile virus infection, we would also like to ask your pediatrician more questions about your child's health at two months, six months, and one year following your child's birth.

The medical care you are given is routine medical care and is not experimental or being done as part of the registry.

Risks or Discomforts

Risks to you from being in this registry are small. You will feel a pin prick when the blood is taken. The hurt will be over quickly. This may leave a small bruise. Also the amount of blood we take is small (approximately 2 teaspoons) and will not harm you at all. All the needles and procedures we will use are germ-free and new. Umbilical cord blood, umbilical cord tissue, and placental tissue are normal products of birth. Collecting these will not cause your child any pain or health risk**.**

In special instances, we may ask to collect a small sample of blood from your child. For example, if you were ill with West Nile virus infection within two weeks before your child's delivery, samples collected at delivery may not tell whether your child was infected in the womb and we may ask to collect a small sample of blood from the child at one month of age. For another example, if the specimens collected at delivery suggest that your child may have been infected with West Nile virus in the womb, we may ask to collect a small sample of blood from the child after six months of age. S(he) will feel a brief pin prick when the blood is taken. The discomfort will be over quickly. This may leave a small bruise. The amount of blood is small (about one fifth of one teaspoon) and will not harm your child at all.

Benefits

Because there is no treatment for West Nile virus, the special testing of samples for West Nile virus infection will not help the doctor take care of your child. The results may help show whether there are health risks from West Nile virus infection during pregnancy.

Confidentiality

We will keep what we talk about today and all test results as private as we can by law. To protect your and your child's privacy, we will keep the records and the blood tube under a code number rather than by your name. Only registry staff will be allowed to look at your information and test results. The code that links a registry number to your name will be kept by registry staff in locked files. Your name or other facts that might point to you will not appear when we talk about this registry or publish its results.

Cost/Payment

West Nile virus testing of the samples from you and your child will be part of the study and will not cost you anything.

Alternatives

You will receive the same care whether or not you join the registry, or if you join the registry and then drop out.

Right to Refuse or Withdraw

You are free to join the registry or not. If you decide to join, you are also free to change your mind at any time for any reason. You will receive the same care whether or not you join, or if you join and then drop out. If you choose to leave the registry, you can ask us to make sure that all of your forms, test results and stored samples are destroyed, and we will follow your instructions.

Persons to Contact

If you have any questions or concerns regarding this surveillance registry, please contact us at any time. Also, if you want to stop participating in the registry at any time, please let us know and we will promptly honor your request.

Daniel R. O'Leary, DVM, DACVPM
Arbovirus Disease Branch
Division of Vector-Borne Infectious Diseases
NCID/CDC
Rampart Rd/Campus West
Fort Collins, CO 80521
DOleary@cdc.gov
Tel: (970) 266-3525

Consent for registry:

If you have read this consent form, had an opportunity to discuss with your health care provider, and agree to participate in the registry, please sign at the space indicated below.

_____ _____
Signature of patient Date

_____ _____
Signature of the physician/representative Date

Thank you for agreeing to be in our registry. We would also like to store your blood, spinal fluid, and other samples to use in the future to look for other causes of encephalitis. We will not use your samples to perform genetic testing or HIV testing. If the testing gives us information that could be important for your health, we will notify you and your doctor about that information. If you decide to leave the registry, we will make sure that all of your forms, test results and stored samples are destroyed. You may still agree to take part in the registry even if you decide you do not want your samples to be stored.

Consent for sample storage and future testing:

If you agree to allow us to store your samples for future testing, please sign below.

_____ _____
Signature of the patient Date

_____ _____
Signature of the physician/representative Date

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Pregnancy-associated West Nile virus (WNV) surveillance form

These data are considered confidential and will be stored in a secure database at the Centers for Disease Control and Prevention, Division of Vector-Borne Infectious Diseases, Fort Collins, CO, 80521

CENTERS FOR DISEASE CONTROL AND PREVENTION

Please return completed form by fax to (970) 266-3568
Contacts: Ms. Stephanie Kuhn: (970) 266-3572, skuhn@cdc.gov
Dr. Dan O'Leary (970) 266-3525, doleary@cdc.gov

Mother's health history

Mother's name:
(Last, First) _____ **DOB:** _____/_____/_____

State of residence: _____ **County of residence:** _____

Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

Race: ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African-American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown

Mother's WNV illness

Date of WNV illness onset: _____/_____/_____

Clinical category of mother's WNV illness: *(check all that apply)*
☐ West Nile Fever ☐ West Nile Meningitis ☐ West Nile Encephalitis ☐ Asymptomatic
☐ Acute Flaccid Paralysis (AFP) ☐ Other Clinical Presentation _____

Mother's pregnancy

Last Menstrual Period: _____/_____/_____ **Estimated delivery date:** _____/_____/_____

Gestation history: Gravida _____ Para _____ SAB _____ TAB _____

Underlying maternal illness: ☐ Yes *(please describe)* ☐ No ☐ Unknown

Complications of pregnancy: ☐ Yes *(please describe)* ☐ No ☐ Unknown

Fetal abnormalities detected in utero: ☐ Yes *(please describe)* ☐ No ☐ Unknown

Did this pregnancy end in miscarriage? ☐ Yes *(date:* _____/_____/_____ *)* ☐ No

Type of delivery: ☐ Vaginal ☐ Forceps/suction ☐ Cesarean section

Maternal temperature at delivery: _____ ☐ Unknown

Blood transfusion given to mother: ☐ Yes ☐ No ☐ Unknown

Does mother plan to breastfeed? ☐ Yes ☐ No ☐ Unknown

Provider information

Provider name: ☐ Dr. ☐ PA ☐ RN ☐ Mr. ☐ Ms. **Phone:** _____
(Last, First) _____ **Fax:** _____

Name of person completing form: *(if different from provider)* **Hospital/facility:** _____
(Last, First) _____ **Phone:** _____

FOR INTERNAL CDC USE ONLY
Mother ID: **State ID:**

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Infant assessment at delivery

Infant's name: *(Last, First)* _____ **DOB:** _____/_____/_____

State of residence: _____ **County of residence:** _____

Gender: ☐ Male ☐ Female **Gestational age at delivery:** _____ weeks by infant exam

Apgar score: 1 min ____ / 5 min ____ **Infant temperature at delivery:** _____ ☐ Unknown

Birth weight: _____ ☐ kg ☐ lbs/oz **Length:** _____ ☐ cm ☐ in **Head circumference:** _____ ☐ cm ☐ in

Seizures: ☐ Yes ☐ No ☐ Unknown **Cataracts:** ☐ Yes ☐ No ☐ Unknown **Skin rash:** ☐ Yes ☐ No ☐ Unknown

Chorioretinitis: ☐ Yes ☐ No ☐ Not assessed ☐ Unknown **Normal tone:** ☐ Yes ☐ No ☐ Unknown

Congenital anomalies: ☐ Yes *(please describe)* ☐ No ☐ Unknown

Focal neurologic deficits: ☐ Yes *(please describe)* ☐ No ☐ Unknown

Hearing evaluation performed: ☐ Normal ☐ Abnormal *(please describe)* ☐ Not Done

Imaging study performed: ☐ No ☐ Yes *(date: ____/____/____ and imaging study type: _____)*

Imaging study result: ☐ N/A ☐ Normal ☐ Abnormal *(if abnormal, please describe)*

TORCH testing: *if positive, please specify test (i.e. PCR, IgG, IgM)*

	Toxoplasmosis	Rubella virus	Cytomegalovirus	Herpes simplex virus	Syphilis	Varicella	Other
positive							
negative							
results pending							
not tested							

Provider information

Provider name: ☐ Dr. ☐ PA ☐ RN ☐ Mr. ☐ Ms. **Phone:** _____
(Last, First) _____ **Fax:** _____

Name of person completing form: *(if different from provider)* **Hospital/facility:** _____
(Last, First) _____ **Phone:** _____

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Infant follow up: ☐ 2 months ☐ 6 months ☐ 12 months

Infant's name: *(Last, First)* _____ **Date of exam:** ____/____/____

Weight: _____ ☐ kg ☐ lbs/oz **Length:** _____ ☐ cm ☐ in **Head circumference:** _____ ☐ cm ☐ in

Infant physical exam: ☐ Normal ☐ Abnormal *(please describe)*

Infant development: ☐ Normal ☐ Abnormal *(please describe)*

Special studies since last follow-up

(Please summarize any results)

CT/other imaging scan: ☐ Yes ☐ No

Hearing evaluation performed: ☐ Yes ☐ No

Dysmorphology exam: ☐ Yes ☐ No

Ophthalmologic exam: ☐ Yes ☐ No

Other *(please describe)***:** ☐ Yes ☐ No

Provider information

Provider name: ☐ Dr. ☐ PA ☐ RN ☐ Mr. ☐ Ms. **Phone:** _____
(Last, First) _____ **Fax:** _____

Name of person completing form: *(if different from provider)* **Phone:** _____
(Last, First) _____ **Fax:** _____

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Specimen Collection and Shipping Instructions
Pregnancy-associated West Nile virus surveillance

Specimens requested:

- ☐ maternal serum, from time of delivery (≥1 ml)
- ☐ cord serum (≥1 ml)
- ☐ colostrum (preferred) or breastmilk (1-3 ml)
- ☐ placental tissue (1 cm^2 full-thickness)
- ☐ cord tissue (1 cm long cross-section)

Collection

Label all specimens below legibly with permanent, non-smearing ink (i.e. Sharpie); please provide:
✓ patient name ✓ date of specimen collection ✓ specimen type

☐ **Maternal serum:**
- within 24 hours prior to- or post-delivery, collect 5 ml blood in red-top or serum-separator tube
- spin/separate serum (1 ml serum needed)
- label clearly, as above

☐ **Cord serum:**
- wipe cord of gross contamination, collect 2-5 ml cord blood in red-top or serum-separator tube
- spin/separate serum (1 ml needed)
- label clearly, as above

Please collect each tissue in a separate, sealed container

☐ **Placental tissue:**
- place small piece (approximately 1 cm^2) full-thickness placenta in threaded, leak-proof vial
- label clearly, as above

☐ **Cord tissue:**
- place small cross-section (approx. 1 cm long) of umbilical cord in threaded, leak-proof vial
- label clearly, as above

☐ **Colostrum (preferred) or breastmilk:**
- clean breast with antiseptic wipe (i.e. chlorhexidine) and let dry
- express 1-3 ml of colostrum or breastmilk and transfer into threaded, leak-proof container (plastic baggies secured with a rubber band tend to leak)
- label clearly, as above

Storage/Packaging

- refrigerate (do not freeze) all specimens as soon as possible (do not fix tissues in formalin; if tissues have been formalin-fixed, please call Stephanie at 970-266-3572)
- when ready to ship, place specimens in a leak-proof bag inside an insulated shipping container on wet ice (blue ice or cold packs)
- label and package all specimens as "diagnostic specimens" (detailed information available at: http://www.cdc.gov/ncidod/dvbid/misc/arboviral_shipping.htm or by calling Stephanie at 970-266-3572)
- include CDC specimen submission form 50.34 (may be faxed upon request, or downloaded at: http://www.cdc.gov/ncidod/dvbid/misc/CDC50_34.pdf)
  - ► the space for "Name, Address and Phone Number of Physician or Organization" should indicate where testing results are to be sent
  - ► complete the form including, at minimum: patient name, date of birth, date of illness onset and date of specimen collection

Shipping

- IMPORTANT! Please ship Monday through Thursday only! CDC is unable to accept deliveries on Saturday.
- ship specimens Priority Overnight, by **FedEx** (FedEx shipping account number available by calling Stephanie at 970-266-3572)

Shipping Address:
CDC/Arbovirus Diagnostic Lab
Attn: Stephanie Kuhn
Foothills Campus
Rampart Road
Fort Collins, CO 80521

***Questions? Please contact Ms. Stephanie Kuhn at (970) 266-3572 or email* skuhn@cdc.gov**